

PATENT  
910000-2020**REMARKS**

Examiner Yu is thanked for courtesies extended during the telephonic interview on October 22, 2003. Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

**I. Status of the Claims and Formal Matters**

Claims 1-7, 16-29 are pending in the application. Claims 1, 2, 5, 7, 22, and 23 are currently amended. Please cancel claims 6, 16-21, 24-29 without prejudice; without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Applicants reserve the right to file divisional applications to pursue the full scope of the claims. No new matter has been added by these amendments. Support is found throughout the specification and from the pending claims. Specific reference is made to U.S. Patent Application Serial No. 09/536,087 (see, for example, page 40), which has been incorporated by reference on page 9 of the specification (lines 1-3), regarding amendments to the claims made herewith, which now recite fragments of TSP-2.

A response to the final office action of March 26, 2003 was filed on July 25, 2003. A notice of appeal was subsequently filed on August 25, 2003. Applicants respectfully request entry of the instant response with the Request for Continued Examination.

**Priority Claim**

The objection to the domestic priority claim under 35 U.S.C. § 119(e) based on provisional application No. 60/127,221 ("the '221 application") is respectfully traversed. Arguments presented in the amendment filed on July 25, 2003 are restated here.

The '221 application discloses a method of treating a subject with a disorder characterized by unwanted cell proliferation by increasing expression of TSP-2. As disclosed on pages 5 and 18 of the '221 application, this can be accomplished by introducing into the subject a genetically modified cell that expresses the molecule. The '221 application states on page 39 that the gene therapy construct "can comprise a slow release matrix in which the gene delivery vehicle is imbedded."

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The Examiner indicated, during the telephonic interview of July 9, 2003, that the rejection under 35 U.S.C. §119(e), regarding the terms "slow release matrix" in the '221 application and "sustained release matrix" in the instant application, was overcome. Therefore, Applicants respectfully request that the objection to the claim of domestic priority under 35 U.S.C. § 119(e) be formally withdrawn.

## **II. The Enablement Rejection Under 35 U.S.C. §112, 1<sup>st</sup> Paragraph, Is Overcome**

Claims 1-7 and 16-29 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is respectfully traversed in view of the amended claims and the remarks herewith.

The Office Action contends that the instant application does not reasonably provide enablement for anti-angiogenic molecules other than TSP-2. Applicants counter that it is well within the purview of the skilled artisan, in an area in which the skill of one in the art is quite high, to identify diseases that are treatable with anti-angiogenic molecules and to treat such diseases using the cell-matrix structure of the invention. During the interview of July 9, 2003, it was expressed that the Applicants are understood to be the first to express anti-angiogenic molecules in an implantable cell-matrix structure to treat diseases, which are treatable by the anti-angiogenic molecules and characterized by excessive proliferation of tissue as claimed in the instant application. Thus, any person of ordinary skill in the art would have a reasonable expectation of success, and as such, it would not require undue experimentation to practice the full scope of the instant invention as claimed.

However, in the interest of advancing prosecution, the amendments presented herewith now direct the scope of the claims to TSP-2 and diseases that are treatable by TSP-2. Therefore, reconsideration and withdrawal of the enablement rejections under 35 U.S.C. §112, 1<sup>st</sup> Paragraph, are respectfully requested.

## **III. The Double Patenting Rejection Is Overcome**

Claim 26 was objected to under 37 C.F.R. 1.75 as being a substantial duplicate of claim 6. Claim 6 was amended in the amendment filed on July 25, 2003, such that it was directed to TSP-2; Claim 26 is directed to thrombomodulin. Claims 6 and 26 have now been canceled in this

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current amendment. Therefore, the double patenting rejection is moot and reconsideration and withdrawal is therefore respectfully requested.

**IV. The Written Description Rejection Under 35 U.S.C. §112, 1<sup>st</sup> Paragraph, Is Overcome**

Claims 27-29 were rejected under 35 U.S.C. §112, 1<sup>st</sup> Paragraph, as allegedly lacking adequate written description. The rejection is respectfully traversed, as claims 27-29 have been canceled. Accordingly, reconsideration and withdrawal of the written description rejection under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, is respectfully requested.

**CONCLUSION**

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance, or at least in better condition for appeal. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,  
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